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HFD-613

NDA 50-619/S-002

NOV 13 1998

Bristol-Myers Squibb Company
Attention: Joseph A. Linkewich, Pharm.D.
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Dr. Linkewich:

Please refer to your supplemental new drug application dated December 12, 1996, received December 17, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MYCOSTATIN" (nystatin lozenges, USP) PASTILLES.

We acknowledge receipt of your submissions dated May 15, 1997, January 29, 1998, and May 19, 1998.

This supplemental new drug application provides for the following changes to the label:

1. The established name has been changed from "nystatin" to "nystatin lozenges, USP."

2. Nearly each instance of "pastille" or "nystatin pastille" has been replaced with "MYCOSTATIN PASTILLE" or "PASTILLE" to reflect that this is the trademark name for this particular product and not a U.S. Pharmacopoeia (USP) recognized dosage form descriptor.

3. "Nystatin pastille" in the **Pregnancy: Teratogenic Effects** subsection has been replaced with "nystatin."

4. "Nystatin" has been replaced with "MYCOSTATIN PASTILLES" in the **ADVERSE REACTIONS** section.

5. A **Nursing Mothers** subsection has been added to the **PRECAUTIONS** section of the label. It reads:

   "It is not known whether nystatin is excreted in human milk. Although gastrointestinal absorption is insignificant, caution should be exercised when nystatin is prescribed for a nursing woman."

6. The **Pediatric Use** subsection of the **PRECAUTIONS** section of the label has been revised to conform to 21 CFR 201.57 (f) (9) (vii). It now reads:

   "The use of MYCOSTATIN PASTILLES has not been systematically studied in pediatric patients."

7. Each instance of “children” has been replaced with “pediatric patients.”

8. “The pastille is contraindicated in those patients with a history of hypersensitivity to any of its components.” has been changed to “MYCOSTATIN PASTILLES are contraindicated in those patients with a history of hypersensitivity to any of the components.” in the CONTRAINDICATIONS section.

9. The statement “CAUTION: Federal law prohibits dispensing without prescription.” has been changed to “Rx only.”

10. Multiple minor editorial changes such as the insertion of the registered trademark symbol, changes in capitalization and changes in bolding have been made.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted May 19, 1998). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated “FINAL PRINTED LABELING” for approved supplemental NDA 50-619/S-002. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

Should a letter communicating important information about this drug product (i.e., a “Dear Doctor” letter) be issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20852-9787

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Ellen C. Frank, R.Ph., Chief, Project Management Staff, at (301) 827-2127.

Sincerely yours,

Mark Goldberger, M.D., M.P.H.
Director
Division of Special Pathogen and Immunologic
Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research